Remarks/Arguments

Claims 1-6 and 11-14 are amended. Claims 7-9 have been canceled. Claim 10 has been withdrawn. It is believed that no new matter has been introduced.

Objection:

Claim 1 has been amended according to the Examiner's suggestion.

Rejection under 35 U.S.C. 112:

Claim 1 is rejected under 35 U.S.C. 112, second paragraph because of insufficient antecedent basis. Applicants have amended claim 1 according to the Examiner's recommendation.
Accordingly, it is requested that the 35 U.S.C. 112 rejection be reconsidered and withdrawn.

Rejection under 35 U.S.C. 103:

The Examiner rejects claims 1-4 and 10-14 over Yamamoto (US5059587), Yamamoto in view of Albert et al (WO 02/10192) and Yamamoto in view of Albert et al and in further view of Stalla et al (European Journal of Endocrinology). Further, Claim 5 and 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Albert et al in view of Kamber B (US Pat. No. 4,603,120)and further in view of Bodmer et al (US Pat. No. 5,639,480). Applicants respectfully traverse.

Yamamoto relates to powdered nasal administration compositions. Furthermore, please note that Yamamoto teaches away from injections because they often cause pain (column 1, lines 18ff). By contrast, the present invention relates to liquid parenteral formulations suitable for injection (see e.g. page 6, third and forth paragraph, examples 1-7). The formulations of the present invention have good stability and tolerability (page 4, second paragraph).

Yamamoto discloses tartaric acid among a list of organic water soluble acids, whereas the present invention specifically teaches compositions comprising tartaric acid. Yamamoto appears to use the organic acid works as absorption promoter in nasal administration, whereas the tartaric acid is primarily used as buffer in the compositions of the present invention (somastatin analogues of the present invention need a pH of ca. 4 to be stable in liquid compositions).

Also, the tartaric acid is the key advantage of the subcutaneous formulation (and differentiates the present invention from the cited prior art).
Other buffer systems in subcutaneous formulations result in irritation of the skin at the site of injection. This problem can be resolved by the use of tartaric acid (page 3, 4 bridging paragraph of the specification). Also, the tartatic acid stabilizes the formulation.

The present invention provides stable and highly tolerable formulations of compounds of formula II. The cited prior art documents contemplate the parenteral application of cyclic somatostatin analogues for similar diseases, but none of the documents mention the problem of pain during intravenous or subcutaneous injection, neither is mentioning the lack of stability of pharmaceutical compositions comprising compounds of formula II.

Accordingly, it is respectfully requested that the 35 U.S.C. 103 rejection be reconsidered and withdrawn.

Applicants respectfully submit that the present claims are in condition for allowance, which action is earnestly solicited.

Respectfully submitted,

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